DURECT Announces Update on Remoxy®

CUPERTINO, Calif., May 10, 2013 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that Pfizer has provided an update on Remoxy as part of their Form 10-Q filing. Pfizer's disclosure is as follows: "In 2005, King Pharmaceuticals, Inc. (King) entered into an agreement with Pain Therapeutics, Inc. (PT) to develop and commercialize Remoxy. In August 2008, the FDA accepted the NDA for Remoxy that had been submitted by King and PT. In December 2008, the FDA issued a "complete response" letter. In March 2009, King exercised its right under the agreement with PT to assume sole control and responsibility for the development of Remoxy. In December 2010, King resubmitted the NDA for Remoxy with the FDA. In June 2011, we and PT announced that a "complete response" letter was received from the FDA with regard to the resubmission of the NDA. We have been working to address the issues raised in the letter, which primarily relate to manufacturing. We met with the FDA in March 2013 to discuss our plan to address the June 2011 "complete response" letter. We received written guidance from the FDA in May regarding required next steps, including additional clinical studies, to address the letter. Based on this guidance, we are considering our options with respect to Remoxy. If we elect to continue development of Remoxy, we would not expect to submit a response to the "complete response" letter before mid-2015."

(Logo: http://photos.prnewswire.com/prnh/20020717/DRRXLOGO)

We understand from Pfizer that additional clinical studies are necessary and include, in part, a pivotal bioequivalence study with the modified formulation to bridge to the clinical data conducted with the original formulation, as well as an abuse potential study with the modified Remoxy formulation.

About Remoxy

Remoxy, an investigational drug, is a unique long acting oral formulation of oxycodone intended to treat moderate-to-severe pain when a continuous, around the clock opioid analgesic is needed for an extended period of time. Based on DURECT's ORADUR technology, which is covered by issued patents and pending patent applications owned by us, Remoxy is designed to discourage common methods of tampering associated with prescription opioid analgesic misuse and abuse.

About DURECT Corporation

DURECT is a specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including Remoxy®, POSIDUR™, ELADUR®, and TRANSDUR®-Sufentanil. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as abuse deterrence, improved convenience, compliance, efficacy and safety for small molecule and biologic drugs. For more information, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding Remoxy, the potential continued development of Remoxy by Pfizer, additional trials and studies, the potential resubmission of the NDA to the FDA, the potential regulatory approval of Remoxy by the FDA, and the potential benefits and uses of Remoxy are forward-looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, the risk that additional trials and studies will not have satisfactory outcomes, the risk that Pfizer will discontinue development of Remoxy, the risk that Pfizer may want to renegotiate terms in the agreements associated with Remoxy, the risk of adverse decisions by regulatory agencies, including product non-approval, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of Remoxy, the potential that the data submitted by Pfizer in response to the complete response letter will not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of Remoxy, and the risk of obtaining marketplace acceptance of Remoxy, avoiding infringing patents held by other parties and securing and defending patents of our own, and managing and obtaining capital to fund our growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on May 3, 2013 under the heading "Risk Factors."

ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

SOURCE DURECT Corporation

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